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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,144	02/09/2004	Philip Chidi Njemanze		1103
23534	7590	10/13/2005		
PHILIP CHIDI NJEMANZE NO 1 URATTA/MCC ROAD P O BOX 302 OWERI, POB302 NIGERIA			EXAMINER GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/773,144	Applicant(s) NJEMANZE, PHILIP CHIDI	
	Examiner Roy D. Gibson	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group II, claims 9-20 in the reply filed on 20 July 2005 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-20 are rejected because they are not presented in a clear step by step manner for the method claimed. Each new subparagraph should present the next step in the method or procedure and begin with an action verb with comments or functional language related to intended results following. See suggested changes below to claim 9 and see the attached patents for clarification of content and format:

9. A method for hypothermia and rewarming of the cerebrospinal fluid in the brain comprising the steps of:

- (a) providing a heat-exchange ventricular catheter;
- (b) simultaneously with (a) providing a drainage ventricular catheter;
- (c) internally implanting the heat exchange catheter into the cerebral ventricle

through a burr hole or twist drill;

whereby the catheters are placed within the ventricle using ventricular catheter introducers anchored into a slit and perforated hole close to the distal ends of the

Art Unit: 3739

catheters respectively, the distal end of the catheter placed above the level of foramen Monro within the ventricle;

(d) connecting the proximal end of the heat-exchange catheter connected to an infusion system;

(e) simultaneously with (d) connecting the proximal end of the drainage catheter to a ventriculo-peritoneal or ventriculo-atrial shunting system;

(f) providing an infusion system containing sterile physiologic solution being at a temperature other than that of the cerebrospinal fluid, wherein a sterile physiologic solution flows in a fluid line into the heat-exchange catheter, the sterile physiologic solution of known chemical constituents, and prepared to preserve cell metabolic energy stores;

(h) providing an infusion pump programmed to deliver the sterile physiologic solution at a predetermined rate;

(i) infusing the sterile physiologic solution directly infused into the cerebral ventricles;

(j) mixing the sterile physiologic solution with cerebrospinal fluid and altering the temperature of the fluid bathing the regulatory centers in the brain, whereby the sterile physiologic solution mixes with the chemistry of the cerebrospinal fluid bathing the regulatory centers in order to maintain neuronal viability;

(k) draining excess cerebrospinal fluid through the drainage catheter to maintain the desired intracranial pressure;

Art Unit: 3739

(l) providing pulsatile movement of cerebrospinal fluid to cause heat exchange spreading throughout the brain and spinal cord;

(m) altering the temperature of cerebrospinal fluid and blood bathing wider brain areas including those involved in regulation of temperature, pain, and emotional stress and further thereby altering central afferents to the neurons in both the preoptic anterior hypothalamus and posterior hypothalamus;

(n) resetting ----- to the end of the claim.

The claims will be more fully examined when the steps are clarified as suggested above.

Conclusion

The following are suggested formats for either a Certificate of Mailing or Certificate of Transmission under 37 CFR 1.8(a). The certification may be included with all correspondence concerning this application or proceeding to establish a date of mailing or transmission under 37 CFR 1.8(a). Proper use of this procedure will result in such communication being considered as timely if the established date is within the required period for reply. The Certificate should be signed by the individual actually depositing or transmitting the correspondence or by an individual who, upon information and belief, expects the correspondence to be mailed or transmitted in the normal course of business by another no later than the date indicated.

Certificate of Mailing

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Art Unit: 3739

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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. () _____ - _____ on _____.
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Please refer to 37 CFR 1.6(d) and 1.8(a)(2) for filing limitations concerning facsimile transmissions and mailing, respectively.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barbut et al. (6,217,552) disclose a medical device for selective spinal cooling (see method claims as an example); Wong et al. (US 2004/0138728) disclose a medical device and method for temperature control of the brain and spinal cord; Larnard et al. (6,660,026) disclose a multi-tipped cooling probe for the brain; Lennox (6,929,656) disclose a method and device for reducing secondary brain injury; Samson et al. (US 2004/0143312) disclose a method and apparatus for providing heat exchange within a catheter body; and Khanna (US 2002/0198579) discloses a selective brain and spinal cord hypothermia method and apparatus.

Note: these patents or patent application publications can be viewed and printed from the web site: www.uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Roy D. Gibson
Primary Examiner
Art Unit 3739

October 3, 2005